## **Summary of Opinions**

- Neurontin is a safe and effective treatment for neuropathic pain and is widely regarded in neurology as one of the most useful medication options for treating chronic neuropathic pain
- The labeling, or professional package insert, for Neurontin approved by FDA at the time of Mr. Smith's death adequately communicated the potential benefits and risks of Neurontin to doctors
- The dosage of Neurontin that Mr. Smith was prescribed at the time of his death was relatively low and was probably insufficient to provide significant pain relief
- Mr. Smith's suicide is most likely attributable to his chronic pain, his depression, and his feelings of hopelessness after being informed shortly before his death that there were no additional treatment options for his severe, chronic pain
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#### **Mr. Smith's Pain Complaints**

1988	1989	1990	1991	1992	1993
Rectal pain with radiation, began after knee surgery     Sealding & Nesbett Urology Clinic, 000006-625NUC-00027	Pr. James Cato  Hand tightness; decreased grip Heritage Medical Associates, 000006-1980-00009  Pelvic pain Heritage Medical Associates, 000006-1980-00009  Pr. Stewart F. Stowers  Right heel pain; right knee pain Nashville Orthopedic Associates, 000006-69AQC-00076  Right hip pain Nashville Orthopedic Associates, 000006-69AQC-00076  Suprapublic pain [groin area] Nashville Orthopedic Associates, 000006-69AQC-00075	Dr. Stewart F. Stowers  Left hip pain extending to groin Nashville Orthopedic Associates, 000006-69AQC-00074  Dr. James Cato  Back pain; upper abdominal burning; tiredness Herrtage Medical Associates, 000006-42HMA-00217  Left jaw and ear pressure/ soreness; left facial numbness Herrtage Medical Associates, 000006-19RD-00013  Dr. Tom Nesbitt  Testicular pain Spalding & Resibrit Urology Clinic, 000006-62SMUC-00025  Dr. David M. Dyer  Chronic right groin/testicular pain	Dr. David M. Dyer  • Left groin pain  000006-6234U/C-00054  Dr. James Cato  • Left jaw, throat, and ear pressure  Heritage Medical Associates, 00006-1PRD-00015-16  • Left shoulder complaints; left hip soreness  Heritage Medical Associates, 000006-1PRD-00015-16	Chronic abdominal pain     Colon & Rectal Surgery Associates, 000006-48CRSA-00009	Dr. Stewart F. Stowers  Severe left knee problems; pain in left ankle Nashville Orthopede Associates, 000006-69NQC-00071  Dr. James Cato  Swelling in hands and ankles; left knee problems Herrlage Medical Associates, 000006-2HMA-00220  Tenderness in left ribs Herrlage Medical Associates, 000006-1PND-00022
1994	1995	1996	1997	1998	1999
Dr. Stewart F. Stowers  • Left knee tightness; pain in left ankle  Rishville Orthopedic Associates, 000006-69AGC-00064	Pr. James Cato  Numbness to left side of face/eye; left tooth problems Heritage Medical Associates, 000006-19RD-00023  Left chest soreness Heritage Medical Associates, 000006-42HMA-00223  Dr. David M. Dyer  Left groin pain  000006-30HMA-00072  Dr. Stewart F. Stowers  Left knee ache Ternessee Orthopedic Associates, 000006-69AQC-00063	Dr. Stewart F. Stowers  • Severe right hip pain  Tennessee Orthopede Associates, 000006-69AQC-00062  Dr. Eugene M. Regan Jr.  • Right hip and groin pain; significant limp  Tennessee Orthopede Allance, 000006-69AQC-00061  • Difficulty sleeping because of hip pain  Tennessee Orthopede Allance, 000006-69AQC-00061  • Left shoulder problems  Tennessee Orthopede Allance, 000006-69AQC-00061  Vicki Bryant, P.T.  • Low back pain; foot symptoms  000006-69AQC-00133  Dr. James Cato  • Lower abdominal pain  Heritage Medical Associates, 000006-30HMA-00029  • Chest pain; arm tingling; numbness to left side of face  Heritage Medical Associates, 000006-30HMA-00030	Pr. Tom Nesbitt  Difficulty urinating, with burning spalding & Nesbitt Unology Clinic, 000006 625NUC-00021  RAH  Lower abdominal pain Colon & Rectal Surgery Associates, 000006-48CRSA-00006  Pressure in rectum, scrotum, and groin Colon & Rectal Surgery Associates, 000006-48CRSA-00006  Dr. Eugene M. Regan Jr.  Right knee pain; low back pain; left knee tightness  Tennessee Orthopaedic Alliance, 000006-32TOA-00046  Dr. Tom Nesbitt  Testicular pain; erectile discomfort  Spalding & Nesbitt Unology Clinic, 000006-62SNUC-00018	Dr. James Cato  Chest discomfort; facial soreness Heritage Medical Associates, 000006-30HMA 00032-33  Dr. Eugene M. Regan Jr.  Left ankle pain Tenesses Orthopede Alliance, 000006-32T0A-00044-45  Increasing right knee pain with significant limp Tenesses Orthopede Alliance, 000006-32T0A-00044-45	Dr. James Cato  Left shoulder soreness and biceps tenderness  Heritage Medical Associates, 000006-30HMA-00036-37  Pain under rib cage  Heritage Medical Associates, 000006-42HMA-00116-117  Dr. Stewart F. Stowers  Right knee stiffness  Tennessee Orthopedic Associates, 000006-32T0A-00023  Baptist Hospital ER  Rib pain; shoulder pain; chest pain; abdominal pain

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#### Mr. Smith's Pain Complaints

2001 2003 2000 2004 2002 **Neurosurgical Associates** Dr. Stewart F. Stowers Dr. Stewart F. Stowers Dr. Stewart F. Stowers Dr. Tom Nesbitt Dr. Frank M. Berklacich · Shocking sensation in Left sacroiliac pain Left shoulder pain Left shoulder pain and weakness Intermittent groin pain; pain · Significant low back and bilateral [hip/buttocks region] Tennessee Orthopedic Alliance, 000006-32TOA-00022 Tennessee Orthopedic Alliance, 000006-32TOA-00021 with urination bilateral legs Sennessee Orthopedic Alliance, 000006-69ADC-00022 Spalding & Nesbitt Urology Clinic, 000006-625NUC-00011 000006-18FMB-00002-3 000006-34NFA-00002 Left knee pain Left knee pain · Left knee flare-up; ankle Tennessee Orthopedic Alliance, 000006-69AQC-00016 Tennessee Orthopedic Alliance, 000006-32TOA-00021 Leg and spine pain Numbness and pins/needles in Dr. James Cato Spalding & Nesbitt Urology Clinic, 000006-62SNUC-00028 Left knee and left ankle pain both legs Pain from back to ankles ssee Orthopedic Alliance, 000006-69AQC-00021 000006-18FMB-00002-3 Tennessee Orthopedic Alliance, 000006-69AQC-00015 Dr. Michael Santi Heritage Medical Associates, 000006-42HMA-00097 Dr. Tom Nesbitt · Weakness and difficulty walking Lower abdominal pain Left shoulder pain; chest 000006-18FMB-00002-3 • Intermittent groin pain Colon & Rectal Surgery Associates, 000006-48CRSA-00005 Dr. James Cato tightness Dr. James Cato Spalding & Nesbitt Urology Clinic, 000006-62SNUC-00012 Sleep impaired by pain Heritage Medical Associates, 000006-42HMA-00089-90 Dr. James Cato Left knee pain Pain across shoulder blades Dr. William A. Shell rage Medical Associates, 000006-30HMA-00042-43 Heritage Medical Associates, 000006-30HMA-00048-49 Sore joints; bladder/prostate Diarrhea due to anxiety and pain Dr. Stuart E. Smith symptoms Persistent low back pain since Neck pain and stiffness; vertigo ritage Medical Associates, 000006-30HMA-00058-59 · Global pain and stiffness Heritage Medical Associates, 000006-30HMA-00050-51 lumbar surgery Dr. Tom Nesbitt Pain in all joints; not sleeping Tennessee Orthopedic Alliance, 000006-32TOA-00002-3 Neck/shoulder pain and spasms; Dr. Paul R. McCombs III Groin pain Heritage Medical Associates, 000006-30HMA-00060-62 · Bilateral radiating leg pain rib soreness; poor sleep Spalding & Nesbitt Urology Clinic, 000006-625NUC-00014 Back and bilateral leg pain Tennessee Orthopedic Alliance, 000006-32TOA-00002-3 Joint pain; back pain/numbness/ Heritage Medical Associates, 000006-30HMA-00052-53 Dr. Jeffrey P. Lawrence Neurosurgical Associates, 000006-34NEA-00021 tingling Dr. Edward S. Mackey Chest soreness Left shoulder pain and inability Back and bilateral leg pain Heritage Medical Associates, 000006-30HMA-00054-55 Increasing left leg pain to lift arm symptoms unchanged · Anxiety and depression Tennessee Orthopedic Alliance, 000006-32TOA-00004 Premier Orthopaedics & Sports Medicine, 000006-120POS-00007 Heritage Medical Associates, 000006-30HMA-00063-64 Neurosurgical Associates, 000006-34NEA-00020 Thoracic spine pain Severe low back and leg pain · Nerve prickling down back; Dr. Gregory Mowery Tennessee Orthopedic Alliance, 000006-32TOA-00015-16 after lumbar surgery pain in legs, knees, ankles after Vertigo; balance problems Back and radicular pain; lumbar surgery Otolaryngology Associates of Tennessee, 000006-110AT-00001 Heritage Medical Associates, 000006-30HMA-00063-64 knee pain Continues with pain and is very nessee Orthopedic Alliance, 000006-32TOA-00005, 9 · Right hamstring spasm Neurosurgical Associates, 000006-1PRD-00408 Heritage Medical Associates, 000006-30HMA-00065-66 Knee pain: worsening bilateral Dr. Tom Nesbitt · Wishes he could die because of leg pain, using wheelchair, not Dr. Michel McDonald sleeping well pain and depression Arthritis Spalding & Nesbitt Urology Clinic, 000006-625NUC-00013 Neurosurgical Associates, 000006-1PRD-00408 versity Medical Center, 000006-40VUM-00009 Increased leg pain after lumbar Dr. Tom Nesbitt Dr. Stuart E. Smith surgery · Difficulty urinating since Neurosurgical Associates, 000006-34NEA-00001 Pain in buttocks radiating back surgery to calves Spalding & Nesbitt Urology Clinic, 000006-625NUC-00009 Tennessee Orthopedic Alliance, 000006-69AQC-00006 Dr. Jeffrey L. Herring Pam Krancer, R.N., C.S., CNRN Bilateral hip and knee pain Tennessee Orthopedic Alliance, 000006-69AQC-00006 Right ankle pain Bilateral leg pain radiating from Tennessee Orthopedic Alliance, 000006-69AQC-00003 Dr. Carl Hampf buttocks, perineal area [groin], and thigh to knees · Hip, back, and bilateral leg pain Neurosurgical Associates, 000006-34NEA-00003 **Powers Chiropractic Clinic** and paresthesias Physical Therapy Evaluation 000006-53CAH-00003-4 Right shoulder pain Frequent joint pain, even in 000006-126MAC-00002-3 • Pain/tingling from lumbar spine replaced joints to ankle; left groin pain University Medical Center, 000006-35UMC-00058 Depressed because of pain and Pain in knees and ankles; pain lack of sleep excruciating and sharp University Medical Center, 000006-35UMC-00076

### **February 6, 2003 Tennessee Orthopaedic Alliance Notes – Dr. Smith**

PATIENT NAME: PATIENT NUMBER: PROVIDER: DOCUMENT TYPE:

SMITH, RICHARD H. 144649

DOS: 02/06/2003 Stuart E. Smith, M.D.

PRACTICE NAME: CHART LOCATION: Office Visit

Tennessee Orthopaedic Alliance

Mr. Smith was down on his rump on 1-2-03, fixing some pipes and he says he has had pain in the buttock region both sides, radiating down to his calves ever since. He said his knees hurt and his right hip is probably worse than his left.

the pain has been persistent since 1-2-03

PHYSICAL EXAMINATION Shows he does not limp. Both knees show 0 to 110° of flexion with no effusion. Stable ligaments. Right hip has fluid range of motion. Both legs 5+ motor, normal sensory exam. Straight leg raising tests are negative.

X-RAYS: X-rays of both knees show hybrid prosthesis, J&J type in place without any loosening, lysis or wear. The right hip is also a hybrid and shows slight eccentricity in the polyethylene component, but otherwise negative. No lysis or loosening

IMPRESSION: Lumbar strain

PLAN: we will start him on Medrol Dosepak and Darvocet. He will see him back in 2 weeks, unless his symptoms have resolved. If he continues to have problems, he needs an x-ray of the lumbar spine at that point.

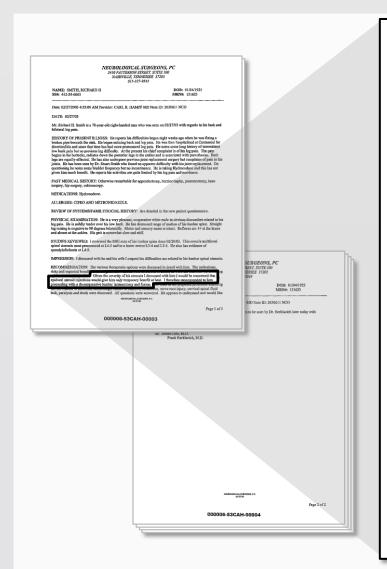
Stuart E. Smith, M.D./jb

000006-69AQC-00006

Mr. Smith was down on his rump on 1-2-03, fixing some pipes and he says he has had pain in the buttock region both sides, radiating down to his calves ever since. He said his knees hurt and his right hip is probably worse than his left.

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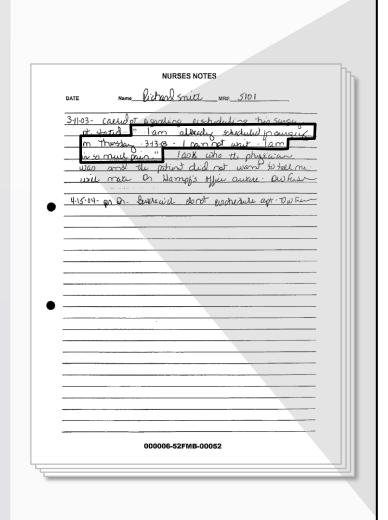
## February 27, 2003 Neurological Surgeons Notes – Dr. Hampf



Given the severity of his stenosis I discussed with him I would be concerned that epidural steroid injections would give him only temporary benefit at best. I therefore recommended to him proceeding with a decompressive lumbar laminectomy and fusion.

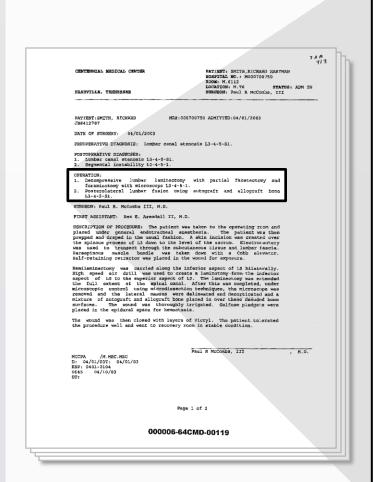
Case 3:05-cv-00444 Document 173-2 Filed 04/27/10 Page 5 of 12 PageID #: 397@ce: 000006-53CAH-00003

#### March 11, 2003 Nurses Notes – Dr. Berklacich



"I am already scheduled for surgery on Thursday 3-13-03 — I cannot wait — I am in so much pain."

## April 1, 2003 Dr. McCombs' Operative Report

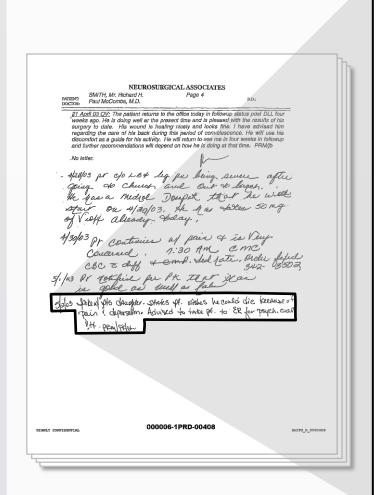


#### **OPERATION:**

- Decompressive lumbar laminectomy with partial facetectomy and foraminotomy with microscope L3-4-5-1.
- 2. Posterolateral lumbar fusion using autograft and allograft bone L3-4-5-S1.

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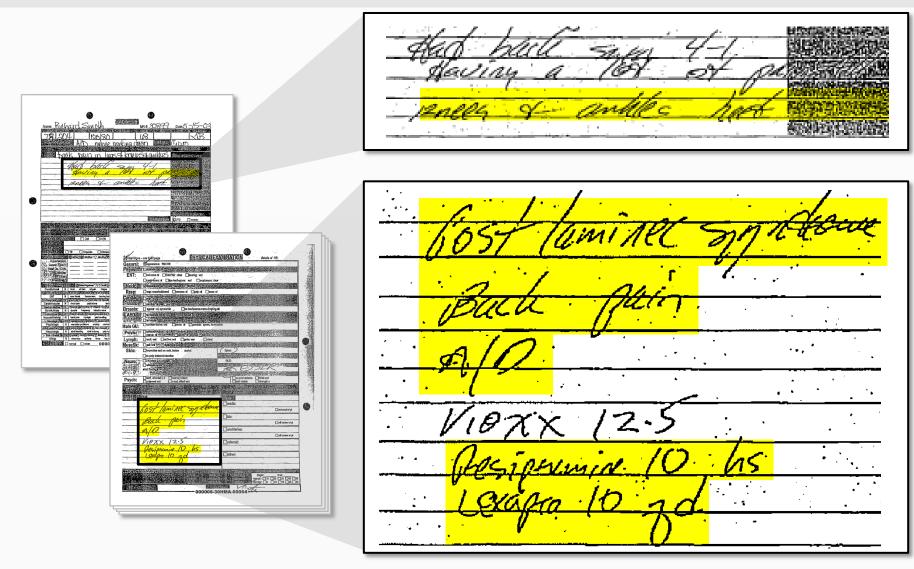
# May 2, 2003 Neurosurgical Associates Notes – Dr. McCombs



Spoke w[ith] p[atien]t's daughter. States p[atien]t wishes he could die because of pain and depression. Advised to take p[atient]t to ER for psych. eval and tx [treatment].

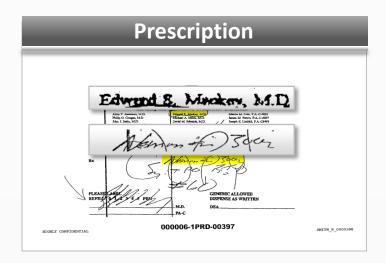
Case 3:05-cv-00444 Document 173-2 Filed 04/27/10 Page 8 of 12 PageID #: 3933urce: 000006-1PRD-00408

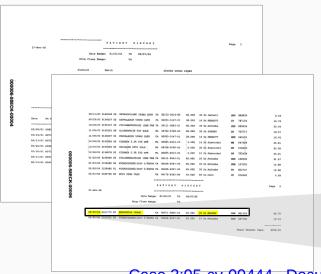
### May 15, 2003 Dr. Cato's Notes



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# March 9, 2004 First Neurontin Prescription





#### **Deposition of Ruth Smith**

- Q. [O]n March 9 of 2004 you became aware that he was on a drug called Neurontin because you physically went and picked up the prescription for him?
- A. I did.
- Q. If he had ever been on the drug Neurontin before March 9 of 2004, is it fair to say you weren't aware of it at the time?
- A. Yes.

Ruth Smith Dep. Tr., April 12, 2007, Pg. 116, Ln. 9-18

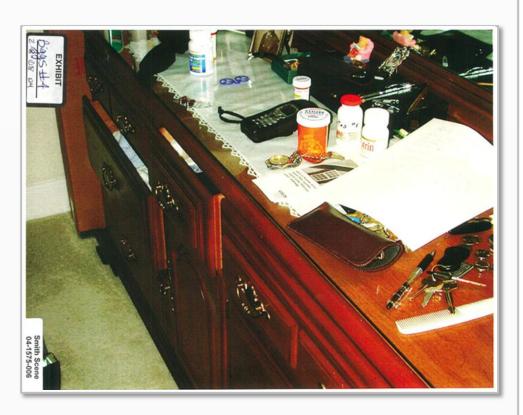
#### **Eckerd Drugs Records**

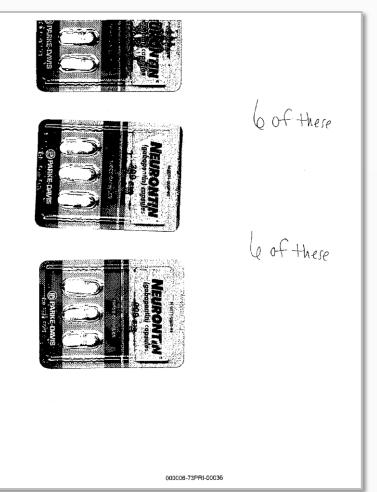
03/09/04 ... NEURONTIN 300MG ... 60 30 Dr. MACKEY

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# Neurontin Supplies Remaining After Mr. Smith's Death





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# Suicide Risk in Elderly Pain Patients

#### ORIGINAL INVESTIGATION

#### Medical Illness and the Risk of Suicide in the Elderly

David N. Juurlink, MD, PhD; Nathan Herrmann, MD; John P. Szalai, PhD; Alexander Kopp, BA; Donald A. Redelmeier, MD, MSc

Buckground: Spicide is a leading cause of death, and rates are especially high among the elderly. Medical ill-nesses may predispose to suicide, but few controlled studies have examined the association between specific dis-eases and suicide. We explored the relationship between treatment for several illnesses and the risk of suicide in elderly patients using a population-based approach.

Mothodsz All Ontario residents 66 years or older who committed suicide between January 1, 1992, and De-cember 31, 2000, were identified from provincial correners' records. Their prescription records during the pre-ceding 6 months were compared with those of living matched controls (1:4) to determine the presence or ab sence of 17 illnesses potentially associated with suicide.

Results: During the 9-year study period, we identified 1354 elderly patients who died of suicide. The most com mon mechanisms involved firearms (28%), hanging (24%) and self-poisoning (21%). Specific illnesses associated with suicide included congestive heart failure (odds ratio [OR],

From the Clinical Epidemiology and Healthcare Research

Departments of Medicine (Drs Junrlink and Redelmeier), Psychiatry (Dr Herrmann), and

Program (Drs Juurlink and Redelmeter) and the

Population Heath Sciences

Clinical Evaluative Sciences (Drs. Junrlink, Scalai, and Redelineser and Mr Kopp),

Toronto, Ontario. The aut

(Dr Szalai). University of enta and the Institute in

1.73; 99% confidence interval [CI], 1.33-2.24), chronic ob structive lung disease (OR, 1.62; 95% CL 1.37-1.92), sei-aure disorder (OR, 2.95; 95% CL 1.89-4.61), urinary incontinence (OR, 2.02: 95% CL 1.29-3.17), anxiety disorder (OR, 4.65; 95% CI, 4.07-5.32), depression (OR, 6.44; 95% CI, 5.45-7.61), psychotic disorders (OR, 5.09; 95% CI, 3.94- 6.59), bipolar disorder (OR, 9.20, 95% Cl, 4.38-19.33), moderate pain (OR, 1.91; 95% Cl, 1.66-2.20), and severe pain (OR, 7.52: 95% CL 4.93-11.46). Treatment for multiple illnesses was strongly related to a higher risk of suicide. Almost half the patients who committed suicide had visited a physician in the preceding week.

Conclusions: Many common illnesses are independently associated with an increased risk of suicide in the elderly. The risk is greatly increased among patients with multiple illnesses. These data may help clinicians to iden-tify elderly patients at risk of suicide and open avenues

Arch Intern Med. 2004:164:1179-1184

problem, ranking as the 11th leading cause of death in the United States and accounteach year. 1.2 Factors associated with an inereased suicide risk include modifiable onditions such as mood disorders. alcoholism, 46 and substance abuse, 7 as well as fixed characteristics such as male sex<sup>8</sup> and advancing age." The elderly generally at-tempt suicide with much higher lethality than younger persons and in many coun-tries kill themselves at a rate higher than any other segment of the population." However, sujcide in the elderly generally receives less attention in the medical literature and news media than suicide in

DICIDE IS A MAJOR BEAUTIL

Suicide among older persons differs in many ways from suicide in younger in-dividuals. 11.33 Because older individuals generally attempt suicide with more le-

that methods, the ratio of completed to at tempted suicides increases substantially with age. Hate Elderly persons who commit suicide are less likely to have discussed their plans beforehand,17 and nonviolent deaths from suicide in the elderly may be mistakenly attributed to illness. In addition, distinctive stresses accompany late life, including retirement, loss of a loved one, social isolation, and an increasing burden of disability, each of which has been suggested as a risk factor for suicide in the elderly, 0.11.17 is

> For editorial comment see page 1171

Many studies have proposed a link be-tween illness and suicide. 25.36 Most of these associations, however, are inferred from uncontrolled case series, and few rigorous stud-ies have been published. 2000 One report of 42 cases found that patients with greater

(REPRINTED) ARCHINTERN MEDIVOL 164, 1UNE 14, 2694 WWW ARCHIN LUNSMED COM-

The risk for suicide among patients with severe pain merits particular attention. Patients with severe pain and inadequate analgesia may view suicide as a means of escape from suffering.

Source: Juurlink, et al., "Medical Illness and the Risk of Suicide Case 3:05-cv-00444 Document 173-2 Filed 04/27/10 Page 1i2 to £ 1i2 eRagoe 1b 1#te 2697 ed, vol. 164, June 14, 2004